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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,811	04/05/2006	Gilles Pauly	C 2708 PCT/US	9595

23657 7590 09/24/2007

COGNIS CORPORATION
PATENT DEPARTMENT
300 BROOKSIDE AVENUE
AMBLER, PA 19002

EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,811	PAULY ET AL.	
	Examiner	Art Unit	
	Helen Nguyen	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22 and 24-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22 and 24-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 6/12/2007. The amendments to the drawings and the specification are acknowledged and the previous drawing objections are withdrawn in light of applicant's remarks. Claims 19, 21-22, 26-27, and 31 are amended. Claim 23 is cancelled. **Claims 19-22 and 24-38** remain pending.

Specification

2. The disclosure is objected to because of the following informalities: the brief description of the drawings on p.14 does not appear to mention Figure 8, although it is described in greater detail in the body of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 27, 31-32, and 38** are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (US Pat No. 5540235).

5. In regards to **Claim 27**, Wilson discloses an apparatus for non-invasive, in vivo determination of the conductivity of nerves in a region of skin, said apparatus comprising:

(a) at least one non-invasive measuring electrode (11) suitable (and thus capable of) for detecting a signal representative of the electrical activity of a sensory nerve of a facial skin substrate in vivo (Col.2: 28-37);

(b) an electronic stimulator (7) connected to at least one stimulation electrode (38);

(c) at least one reference electrode (11), best seen in Figure 1 (Col.2: 30);

(d) a circuit connected to the at least one non-invasive measuring electrode, the electronic stimulator, and the at least one reference electrode for evaluating signals detected by said electrodes, the circuit comprising at least one amplifying element (51), at least one processing element (53), and at least one microprocessor or computer (1) that includes at least one recording element (memory), best seen in Figure 6, wherein said circuit is capable of creating and displaying a curve representative of differentials in the signals detected by the at least one non-invasive measuring electrode before and after a stimulation as a function of time. It is noted that Wilson discloses all the claimed structural elements and are thus capable of any use recitation.

6. In regards to **Claim 31**, Wilson discloses at least two non-invasive measuring electrodes, best seen in Figure 1, wherein at least one non-invasive measuring electrode is capable of measuring impedance of the facial skin substrate.

7. In regards to **Claim 32**, Wilson discloses at least one adjustable voltage generator (35) associated with at least one transmitting aerial (15) erected in proximity to the at least one non-invasive measuring electrode (11) capable of measuring impedance, best seen in Figure 1A and 3A.

8. In regards to **Claim 38**, Wilson discloses the at least one processing element comprises an analog/digital converter (52).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. **Claims 19-22, 24-27, 30-32, and 38** rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (US Pat No. 5540235) in view of Zealear et al (US Pat No. 4817628).

11. In regards to **Claim 19**, Wilson discloses a method for non-invasive, in vivo determination of the conductivity of nerves in a region of skin, said method comprising:

(a) providing a skin substrate to be analyzed;

(b) applying a first non-invasive electrode (11) to a first measuring point of the skin substrate for detecting the electrical signals from the nerves in the region of the first measuring point;

(c) applying a second non-invasive electrode (11) to a second measuring point of the skin substrate for detecting the electrical signals from the nerves in the region of the second measuring point, best seen in Figure 1;

(d) subjecting the skin substrate to stimulation (7) in vivo;

(e) recording the electrical signal detected by the first and second non-invasive electrodes (Col.2: 28-36);

(f) analyzing the electrical signals for the conductivity of the nerves in the region of the first and second measuring points (Col.2: 28-42) with an evaluation circuit (abst), the evaluation circuit comprising at least one amplifying element (51), at least one processing element (53), and at least one microprocessor or computer (1) including at least one recording element (memory) and a display (Figure 1), best seen in Figure 6.

12. However, Wilson does not disclose the method for determining the conductivity of nerves in a facial region of the skin. Zealear et al disclose electrodes placed on a facial skin substrate, best seen in Figure 1 (abst) to determine the conductivity of the nerves (Col.10: 22: 47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Wilson to determine the conductivity of nerves in a facial region of the skin as taught by Zealear et al as a useful application of nerve conduction studies.

13. In regards to **Claim 20**, Wilson discloses the stimulation (7) (Col.6: 42-43) comprises electrical stimulation (Col.2: 28-35).

14. In regards to **Claim 21**, Wilson in combination with Zealear et al disclose the electrical stimulation (7) is provided by a stimulation circuit comprising at least two stimulation electrodes (38) in contact with an area of the facial skin substrate subject to the stimulation and an electrical stimulator (33) connected to the microprocessor (1), best seen in Figures 1 and 3 (Col.6: 42-49).

15. In regards to **Claim 22**, Wilson in combination with Zealear et al disclose the method above but do not explicitly disclose the facial skin substrate is further subjected to stress. Zealear et al disclose that the nerve conduction is tested against the effects of a stress or chemical agent (Col.12: 31-33; Col.13: 5-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Wilson as modified by Zealear et al to have the facial skin substrate further subjected to a stress and the electrical signals detected by the first and second non-invasive electrodes with the stress is compared to the electrical signals detected by the first and second non-invasive electrodes without the stress to enhance the method by determining the effects of the stress on the nerve conduction

16. In regards to **Claim 24-25**, Zealear et al disclose the first non-invasive electrode is positioned such that it is capable of capable of transmitting signals representative of the electrical activity of at least of one branch of a facial trigeminal nerve selected from the group consisting of an ophthalmic branch, a maxillary branch, a mandibular branch and combination thereof, and in particular the maxillary branch. Although Zealear et al do not explicitly disclose electrical contact with the maxillary branch, it is obvious to one of ordinary skill in the art that the placement of said electrodes, best seen in Figure 1, would enable electrical contact with said maxillary branch due to its known location on the face coinciding with that of said electrodes

17. In regards to **Claim 26**, Wilson in combination with Zealear et al disclose applying a weak alternating current (Col.5: 50) to the first non-invasive electrode and measuring the impedance of the facial skin substrate.

18. In regards to **Claim 27**, Wilson discloses an apparatus for non-invasive, in vivo determination of the conductivity of nerves in a region of skin, said apparatus comprising:

(a) at least one non-invasive measuring electrode (11) suitable for detecting a signal representative of the electrical activity of a sensory nerve of a skin substrate in vivo (Col.2: 28-37);

(b) an electronic stimulator (7) connected to at least one stimulation electrode (38);

(c) at least one reference electrode (11), best seen in Figure 1 (Col.2: 30);

(d) a circuit connected to the at least one non-invasive measuring electrode, the electronic stimulator, and the at least one reference electrode for evaluating signals detected by said electrodes, the circuit comprising at least one amplifying element (51), at least one processing element (53), and at least one microprocessor or computer (1) that includes at least one recording element (memory), best seen in Figure 6.

19. However, Wilson does not explicitly disclose sensing an electrical signal of a sensory nerve of a facial skin substrate and a curve representative of change in the signal detected by the at least one non-invasive measuring electrode after a stimulation, as a function of time, is created and displayed. Zealear et al disclose detecting an electrical signal of a sensory nerve of a facial skin substrate, best seen in Figure 1, as well as displaying various waveforms as a result of each stimulus for monitoring (Col.10: 57-60). Wilson also discloses displaying graphical information relating to the electrical signals (abst).

20. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wilson to sense the electrical signal of a sensory nerve of a facial skin substrate as taught by Zealear et al as a useful application of the electrical

sensing device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wilson to display a curve representative of change in the signal detected by the at least one non-invasive measuring electrode before and after a stimulation, as a function of time as taught by Zealear et al to effectively communicate relevant data such as the change caused by the stimulation.

21. In regards to **Claim 30**, Wilson or Wilson in combination with Zealear et al disclose the apparatus above but does not disclose at least one non-invasive measuring electrode connected to an adjustable connected to an adaptable holder. Zealear et al teach an adaptable holder (66) and an adjustable arm having a first and second end, wherein the first end is connected to the adaptable holder, and wherein a least one electrode is connected to the second end, best seen in Figure 1, as an effective means to secure the electrodes to the head to allow electrical contact with the facial skin and nerves (Col. ¶0035). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place at least one non-invasive measuring electrode of Wilson or Wilson in combination with Zealear et al on an adjustable arm connected to an adaptable holder described above, as taught by Zealear et al, as an effective means to secure the at least one non-invasive measuring electrode to the head for the desired facial nerve analysis.

22. In regard to **Claims 31-32 and 38**, see the rejection above.

23. **Claims 28-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Dunseath, Jr (US Pat No. 5003978).

24. Wilson discloses at least one non-invasive measuring electrode above but does not disclose said electrode as non-polarizable or comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof. Dunseath, Jr teach the use of a non-polarizable electrode for advantages such as the ability to withstand high voltage overloads (Col.1: 36-44) comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof (Col.5: 1-5) as effective materials for said non-polarizable electrode. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the at least one non-invasive measuring electrode of Wilson non-polarizable and comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof, as taught by Dunseath, Jr, as an effective means to obtain the benefits associated with use of a non-polarizable electrode such as high voltage capacity.

25. **Claims 33-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Miyata et al (US Pat No. 6026321).

26. In regards to **Claim 33**, Wilson discloses at least one amplifying element comprising at least one preamplifier (51). However, Wilson does not disclose the at least one preamplifier having a high input impedance over a voltage range of from -3 to +3 volts. Miyata et al disclose an amplifier having a high input impedance over a voltage range of from -3 to +3 volts (Col.6) as

an effective value for skin measuring electrodes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to having the at least one preamplifier of Wilson have a high input impedance over a voltage range of from -3 to +3 volts as taught by Miyata as an effective value for the skin measuring application.

27. In regards to **Claim 34**, Wilson discloses the at least one preamplifier (51) is connected directly to the at least one reference electrode through Pins 45 and 46 (Col.8: 23-31), best seen in Figure 4d.

28. In regards to **Claim 35**, Wilson discloses the at least one preamplifier (51) is connected directly to the non-invasive measuring electrode through Pins 45 and 46 (Col.8: 23-31), best seen in Figure 4D.

29. **Claims 36-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Miyata et al, further in view of Bergman et al (US Pat No. 4257010).

30. In regards to **Claim 36**, Wilson as modified by Miyata et al above discloses at least one preamplifier connected to the non-invasive measuring electrode but do not disclose the at least one preamplifier is connected to the non-invasive measuring electrode by a shielded cable. Bergman et al disclose connecting wires (13a,b) surrounded by shielding (16) to prevent interference between the wires (Col.5: 44-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect the at least one

preamplifier to the non-invasive measuring electrode by a shielded cable to prevent unwanted interference between proximal connecting wires.

31. In regards to **Claim 37**, Wilson as modified by Miyata et al and Bergman et al above disclose the shielded cable comprises a shield connected to an output of the at least one amplifying element (Col.5: 50-58).

Response to Arguments

32. Applicant's arguments with respect to claims 23-22 and 24-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/HQN/

/MAX HINDENBURG/
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